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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/557,119	04/24/2000	Dimitri Kanevsky	YOR000023US1	8968

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EXAMINER

GOODWIN, JEANNE M

ART UNIT

PAPER NUMBER

2841

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

AC

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/557,119	KANEVSKY ET AL.
Examiner Jeanne-Marguerite Goodwin	Art Unit 2841	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM

#### THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 01 August 2002.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-40 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-40 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on 27 February 2002 is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

### ***Drawings***

2. The corrected or substitute drawings were received on Feb. 27, 2002. These drawings are approved.

### ***Claim Objections***

3. Claims 1, 6, 8 and 26 are objected to because of the following informalities:
  - a. Claim 1, line 5: "each" should be deleted and --at least one-- should be added after "said" for antecedent basis.
  - b. Claim 6, line 1: "said activity" lacks antecedent basis.
  - c. Claim 8, line 2: --sleep analyzing-- should be added before "server" for antecedent purposes.
  - d. Claim 26, lines 1-2: "labeled" should be deleted for antecedent purposes.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. . . Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regards to claim 7, line 2: the claim language is confusing and indefinite because it is unclear whether applicant is claiming the eyelid sensors in addition to the at least one sensor.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 15-19 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,836,219 to Hobson et al. [hereinafter Hobson].

Hobson discloses an electronic sleep state reporting device (10) including two movement sensors (18/20), wherein the sensors (18/20) produce two distinct analog electric signals representative of eye movements and head movements, respectively. The signals are amplified by standard operational amplifiers (22/24), yielding signals (25/27), which are then filtered by filters (26/28). Filters (26/28) consists of transistors which converts analog signals to a digital signals (34/36). The digital signals are input to noise filters (37/39) and then to an electric comparison filter (38) (also called a sleep state predictor) which compares digital movement reports to predetermined criteria indicative of sleep states. The comparison filter (38) can be a computer (e.g., personal computer) with suitable software program to perform indications of

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REM, non-REM and wakefulness operations, or can be an electronic circuit containing a ROM, committed to make those operations. Furthermore, the comparison filter (38) includes an output (40) for indicating sleep state, e.g., a chart recorder.

***Claim Rejections - 35 USC § 103***

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1, 4, 8-13, 21-24, and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,928,133 to Halyak [hereinafter Halyak].

Halyak discloses a user responsive sleep monitoring and awakening device comprising at least one wire or wireless sleep sensor (12) (see column 4, lines 5-10) which sends data to a control unit (14) having a microprocessor/local computer (20), wherein microprocessors inherently include some form of computer readable program code means, and wherein, the microprocessor (20) stores and compares the data and the control unit (14) allows the user to pick a time interval in which to awaken or to choose a time after which they wish to awaken, the device will then wait until one of these optimal wake up points is reached and then activate an alarm (22), a clock (18) having a timer chip, a display (27), an optional printer to allow the user to have a permanent record of the data from sensor (12) and an optional central processor/network computer may be used by a supervisor of a group to wake the next individual who experiences an optimal wake-up point (see column 5, lines 39-44). In this sense the central processor could act as a sleep analyzer. Furthermore, it has been noted that wide variety of

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physiological data could be used to accomplish the purpose of the invention, such as EEGs (the electroencephalogram (EEG) is a recording of the low-voltage electrical activity produced in specific regions of the brain. The EEG provides a powerful tool for studying both normal and abnormal brain function, and has been commonly used to measure and define wakefulness and sleep), movement, etc., or any other of the common parameters monitored by sleep researchers. With regards to the receiver, the control unit (14) would have a receiving means in order to be able to receive the sleep activity signals sent from the sensor (12). Halyak discloses all the subject matter claimed by applicant with the exception of the limitations stated in claim 1, i.e., the alarm device being remote.

With respect to the limitation stated in claim 1, i.e., the alarm device being remote; It would have been obvious to one having ordinary skill in the art at the time the invention was made to separate the alarm from the control unit, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. See *Nerwin v. Erlichman*, 168 USPQ 177, 179.

With respect to claims 21-24: the method steps will be met during the normal assembly of the apparatus stated above.

10. Claims 2, 3, 5-7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halyak in view of US Patent 5,902,250 to Verrier et al. [hereinafter Verrier].

Halyak discloses a device as stated above with regards to claims 1, 4, and 8-13. Halyak discloses all the subject matter claimed by applicant with the exception of the limitation stated in claim 2, i.e., the brain activity signals identifies periods of slow wave sleep; the limitation stated

in claim 3, i.e., the brain activity signals identifies periods of non-REM sleep; the limitation stated in claim 5, i.e., the at least one sensor measures brain activity using polysomnography; the limitation stated in claim 6, i.e., the at least one sensor is a plurality of sensors; the limitation stated in claim 7, i.e., the sleep activity is eye movement and the use of eyelid sensors; and the limitation stated in claim 14, i.e., the selected sleep activity is non-REM sleep.

With respect to the limitation stated in claims 2, 3 and 14: Verrier teaches the different types of sleep states which include rapid eye movement (REM) state and non-REM, or slow wave sleep (SWS). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify by adding the parameters of identifying non-REM and slow wave sleep (SWS), as taught by Verrier, to the microprocessor, as taught by Halyak, in order to monitor additional sleeping states commonly monitored by sleep researchers.

With respect to the limitation stated in claim 5: Verrier teaches monitoring signals (EEG, etc.) through the use of a portable polysomnography system as a way of receiving and recording signals for later analysis and study. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to add the portable polysomnography, as taught by Verrier, to the device, as taught by Halyak, as way of receiving and recording signals for later analysis and study.

With respect to the limitation stated in claim 6: It has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. See *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

With respect to the limitation stated in claim 7: Verrier teaches monitoring the frequency of eyelid movements which includes applying an eyelid sensor to the eyelid. Therefore, it would

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have been obvious to a person having ordinary skill in the art at the time the invention was made to replace the sensor, as taught by Halyak, with the eyelid sensor, as taught by Verrier, since both are alternative types of sensors which will provide the same function, if one is replaced with the other, of monitoring sleep activity.

11. Claims 25-28, 30, and 35-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Halyak and Verrier as applied to claims 1-14 and 21-24 above, and further in view of Hobson. The combination of Halyak and Verrier disclose a device as stated above with regards to claims 1-14, and 21-24. The combination of Halyak and Verrier disclose all the subject matter claimed by applicant with the exception of the limitations stated in claims 35, i.e., a prototype chart and labeling periods in the prototype chart.

With regards to the limitations stated in claim 35: Hobson an electronic sleep state reporting device (10) comprising a comparison filter (38) having an output (40) for indicating sleep state, e.g., a chart recorder. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to replace the printer, as taught by the combination of Halyak and Verrier, with the chart recorder, as taught by Hobson, since both are alternative types of recording devices which will provide the same function, if one is replaced with the other, of illustrating the sleep state of the user.

With respect to claims 25-31: the method steps will be met during the normal assembly of the apparatus stated above.

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*Response to Arguments*

12. Applicant's arguments filed Aug. 1, 2002 have been fully considered but they are not persuasive.

In response to Applicant's argument that the prior art of record does not include certain features of Applicant's invention, the limitations on which the Applicant relies (i.e., the sleep analyzing server analyzes the signal and *provides the analysis back* to the local computer which determines the best time to wake the sleeper) are not stated in the claims. It is the claims that define the claimed invention, and it is claims, not specification that are anticipated or unpatentable. See *Constant v. Advance Micro-Devices, Inc.*, 7 USPQ2d 1064.

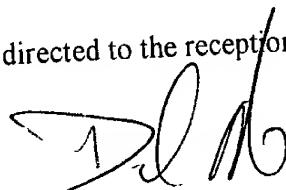
*Conclusion*

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art cited in the PTO-892 disclose related devices. US Patent 5,259,390 to MacLean discloses a method and apparatus to monitor sleep behavior; US Patent 6,047,203 to Sackner et al. physiologic signs feedback system; US Patent 5,846,206 to Bader discloses a method and apparatus for monitoring and estimating the awakeness of a person; US Patent 4,999,772 to Bowman et al. discloses a sleep screening system for recording on tape, transcription and charting a plurality of physiologic data channels; WO009714354A2 to Griebel discloses a method and device for the quantitative analysis of sleep disturbances; and EP1163877A1 to Barron et al. discloses a system for body activity detection and processing.

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14. Any inquiry concerning this communication or earlier communication from the examiner should be directed to Examiner Jeanne-Marguerite Goodwin whose telephone number is (703) 305-0264. The examiner can normally be reached on Monday-Friday (9am-6pm), alternate Fridays off. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-7724. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.



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Feb. 5, 2003